

Docket: P-9091.04



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Jahns et al	)	Art Unit:		
Serial No.:	10/724,978	) )	Examiner:		
Filed:	12-01-2003	)			
For:	METHOD AND SYSTEM FOR NERVE STIMULATION AND CARDIAC SENSING PRIOR TO AND DURING A MEDICAL PROCEDURE				

# INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## Dear Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application.

Consideration of each of the documents listed on the attached Form 1449 is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicant further requests that a copy of the Form 1449, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Respectfully submitted,

Scott E. Jahns et al By their Representatives,

Daniel W. Latham

Attorney for Applicants Registration No. 30,401

Telephone: (763) 391-9661

Customer No.: 27581

# P-9091.04

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

## INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Jahns et al

METHOD AND SYSTEM FOR NERVE STIMULATION AND CARDIAC SENSING PRIOR TO AND DURING A MEDICAL

**PROCEDURE** 

Serial No.: Filed:

10/724,978 12-01-2003

CERTIFICATE OF MAILING UNDER 37 CFR 1.8: I hereby certify that this INFORMATION DISCLOSURE STATEMENT and the paper(s), as described herein, are being deposited in the U.S. Postal Service, as first class mail, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 12+L day of February\_\_\_\_, 2004.

> Signature Barbara J. Lakaner

Printed Name

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

We are transmitting herewith the attached:

☑ Information Disclosure Statement Transmittal

 $\boxtimes$ Information Disclosure Statement

PTO FORM 1449

Copy of cited Foreign Patents and Other documents

□ Return Postcard

### **FEE CALCULATION**

↓ \$ 00.00 Pursuant to 37 CFR §1.97(b)
\$ 00.00 Pursuant to 37 CFR §1.97(c) with Certification
\$ 00.00 Pursuant to 37 CFR §1.97(e) with Certification
\$240.00 Pursuant to 37 CFR §1.97(c) without Certification
\$130.00 Pursuant to 37 CFR §1.97(d) with Certification
•

Applicant hereby petitions for a consider this petition therefor.

months' extension of time. If an additional extension of time is required, please

 $\boxtimes$ 

Applicant believes that no extension of time is required. However, if an extension of time is required, please consider this a petition therefor to provide for the possibility that applicant has inadvertently overlooked the need for an extension of time.

 $\boxtimes$ Please charge any additional fees or credits to Deposit Account No. 13-2546 which may have been overlooked on this Amendment Transmittal with regard to this filing. A duplicate of this transmittal is enclosed.

2/11/2004

Daniel W. Latham Reg. No. 30,401

Telephone: (763) 391-9661 Customer No.: 27581

Page 1 of 4

INFORMATION TOUSCLOSURE 2004 STATEMENT Atty. Docket No.: P-9091.04 Serial No.: 10/724,978

Applicant(s): Jahns et al

Filing Date: 12-01-03 Group:

# **U.S. PATENT DOCUMENTS**

5,014,698 5,044,367 5,056,519 5,129,392 5,199,428 5,203,326 5,243,980 5,292,338 5,330,507 5,334,221 5,354,318 5,356,425	05-14-1991 09-03-1991 10-15-1991 07-14-1992 04-06-1993 04-20-1993 09-14-1993 03-08-1994 07-19-1994 08-02-1994 10-11-1994	Cohen Endres et al Vince Bardy et al Obel et al Collins Mehra Bardy Schwartz Bardy	128 128 128 128 128 128 128 607 607 607	419D 419R 419G 419D 419C 419PG 6 5	
5,056,519 5,129,392 5,199,428 5,203,326 5,243,980 5,292,338 5,330,507 5,334,221 5,354,318 5,356,425	10-15-1991 07-14-1992 04-06-1993 04-20-1993 09-14-1993 03-08-1994 07-19-1994 08-02-1994	Vince Bardy et al Obel et al Collins Mehra Bardy Schwartz Bardy	128 128 128 128 128 607 607	419G 419D 419C 419PG 6 5	
5,129,392 5,199,428 5,203,326 5,243,980 5,292,338 5,330,507 5,334,221 5,354,318 5,356,425	07-14-1992 04-06-1993 04-20-1993 09-14-1993 03-08-1994 07-19-1994 08-02-1994	Bardy et al Obel et al Collins Mehra Bardy Schwartz Bardy	128 128 128 607 607	419D 419C 419PG 6 5 14	
5,199,428 5,203,326 5,243,980 5,292,338 5,330,507 5,334,221 5,354,318 5,356,425	04-06-1993 04-20-1993 09-14-1993 03-08-1994 07-19-1994 08-02-1994	Obel et al Collins Mehra Bardy Schwartz Bardy	128 128 607 607 607	419C 419PG 6 5 14	
5,203,326 5,243,980 5,292,338 5,330,507 5,334,221 5,354,318 5,356,425	04-20-1993 09-14-1993 03-08-1994 07-19-1994 08-02-1994	Collins Mehra Bardy Schwartz Bardy	128 607 607 607	419PG 6 5 14	
5,243,980 5,292,338 5,330,507 5,334,221 5,354,318 5,356,425	09-14-1993 03-08-1994 07-19-1994 08-02-1994	Mehra Bardy Schwartz Bardy	607 607 607	6 5 14	
5,292,338 5,330,507 5,334,221 5,354,318 5,356,425	03-08-1994 07-19-1994 08-02-1994	Bardy Schwartz Bardy	607 607	5 14	
5,330,507 5,334,221 5,354,318 5,356,425	07-19-1994 08-02-1994	Schwartz Bardy	607	14	
5,334,221 5,354,318 5,356,425	08-02-1994	Bardy		+	
5,354,318 5,356,425			607	1.4	
5,356,425	10-11-1994		1	14	
		Taepke	607	22	
	10-18-1994	Bardy et al	607	14	
5,507,784	04-16-1996	Hill et al	607	14	
5,403,356	04-04-1995	Hill et al	607	14	•
5,501,703	03-26-1996	Holsheimer et al	407	46	
5,540,732	07-30-1996	Testerman	607	42	
5,549,655	08-27-1996	Erickson	607	42	
5,578,061	11-26-1996	Stroetmann et al	607	4	
5,620,468	04-15-1997	Mongeon et al	607	5	
5,651,378	07-29-1997	Matheny et al	128	898	
5,690,681	11-25-1997	Geddes et al	607	2	
5,700,282	12-23-1997	Zabara	607	9	
5,792,187	08-11-1998	Adams	607	5	
5,913,876	06-22-1999	Taylor et al	607	2	
5,916,239	06-29-1999	Geddes et al	607	14	-
5,964,789	10-12-1999	Karsdon	607	39	
6,006,134	12-21-1999	Hill et al	607	9	
6,043,273	03-28-2000	Duhaylongsod	514	478	
6,060,454	05-09-2000	Duhaylongsod	514	26	
6,073,048	06-06-2000	Kieval et al	607	17	
6,087,394	07-11-2000	Duhaylongsod	514	478	
6,101,412	08-08-2000	Duhaylongsod	607	2	
6,127,410	10-03-2000	Duhaylongsod	514	478	
	5,507,784 5,403,356 5,501,703 5,540,732 5,549,655 5,578,061 5,620,468 5,651,378 5,690,681 5,700,282 5,792,187 5,913,876 5,916,239 5,964,789 6,006,134 6,043,273 6,060,454 6,073,048 6,087,394 6,101,412	5,507,784         04-16-1996           5,403,356         04-04-1995           5,501,703         03-26-1996           5,540,732         07-30-1996           5,549,655         08-27-1996           5,578,061         11-26-1996           5,620,468         04-15-1997           5,690,681         11-25-1997           5,700,282         12-23-1997           5,913,876         06-22-1999           5,964,789         10-12-1999           6,043,273         03-28-2000           6,060,454         05-09-2000           6,087,394         07-11-2000           6,101,412         08-08-2000	5,507,784         04-16-1996         Hill et al           5,403,356         04-04-1995         Hill et al           5,501,703         03-26-1996         Holsheimer et al           5,540,732         07-30-1996         Testerman           5,549,655         08-27-1996         Erickson           5,578,061         11-26-1996         Stroetmann et al           5,620,468         04-15-1997         Mongeon et al           5,651,378         07-29-1997         Matheny et al           5,690,681         11-25-1997         Geddes et al           5,700,282         12-23-1997         Zabara           5,792,187         08-11-1998         Adams           5,913,876         06-22-1999         Taylor et al           5,964,789         10-12-1999         Karsdon           6,006,134         12-21-1999         Hill et al           6,043,273         03-28-2000         Duhaylongsod           6,060,454         05-09-2000         Duhaylongsod           6,087,394         07-11-2000         Duhaylongsod           6,101,412         08-08-2000         Duhaylongsod	5,507,784         04-16-1996         Hill et al         607           5,403,356         04-04-1995         Hill et al         607           5,501,703         03-26-1996         Holsheimer et al         407           5,540,732         07-30-1996         Testerman         607           5,549,655         08-27-1996         Erickson         607           5,578,061         11-26-1996         Stroetmann et al         607           5,620,468         04-15-1997         Mongeon et al         607           5,651,378         07-29-1997         Matheny et al         128           5,690,681         11-25-1997         Geddes et al         607           5,700,282         12-23-1997         Zabara         607           5,913,876         06-22-1999         Taylor et al         607           5,916,239         06-29-1999         Geddes et al         607           5,964,789         10-12-1999         Karsdon         607           6,006,134         12-21-1999         Hill et al         607           6,060,454         05-09-2000         Duhaylongsod         514           6,073,048         06-06-2000         Kieval et al         607           6,101,412         08-08-2000	5,507,784         04-16-1996         Hill et al         607         14           5,403,356         04-04-1995         Hill et al         607         14           5,501,703         03-26-1996         Holsheimer et al         407         46           5,540,732         07-30-1996         Testerman         607         42           5,549,655         08-27-1996         Erickson         607         42           5,578,061         11-26-1996         Stroetmann et al         607         4           5,620,468         04-15-1997         Mongeon et al         607         5           5,651,378         07-29-1997         Matheny et al         128         898           5,690,681         11-25-1997         Geddes et al         607         2           5,700,282         12-23-1997         Zabara         607         9           5,913,876         06-22-1999         Taylor et al         607         2           5,916,239         06-29-1999         Geddes et al         607         14           5,964,789         10-12-1999         Karsdon         607         39           6,006,134         12-21-1999         Hill et al         607         9           6,043,273

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Page 2 of 4

FEB 1 7 2004

INFORMATION DISCLOSURE STATEMENT

Atty. Docket No.: P-9091.04	Serial No.: 10/724,978

Applicant(s): Jahns et al

Filing Date: 12-01-03 Group:

# **U.S. PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Name	Class	SubClass	Filing Date If Appropriate
	6,141,589	10-31-2000	Duhaylongsod	607	10	
	6,184,239	02-06-2001	Puskas	514	346	
	5,836,994	11-17-1998	Bourgeois	607	40	
	4,960,133	10-02-1990	Hewson	128	784	
	4,304,239	12-08-1981	Perlin	128	642	
	4,640,298	02-03-1987	Pless et al	128	784	
	5,540,730	07-30-1996	Terry Jr. et al	607	040	
	5,330,515	07-19-1994	Rutecki et al	607	46	
	5,928,272	07-27-1999	Adkins et al	607	45	
	5,611,350	03-18-1997	John	128	731	
	5,571,150	11-05-1996	Wernicke et al	607	72	
	5,052,390	10-01-1991	Hewson	128	419D	
	5,056,532	10-15-1991	Hull et al			

# FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	SubClass	Trans	Translation	
					Yes	No	
DE 28 11 325	09-27-1979	Germany					
EP 0 589 252	09-01-1993	European					
WO 92/11064	07-09-1992	PCT					
WO 97/40885	11-06-1997	PCT					
WO 99/07354	02-18-1999	PCT					
WO 99/09971	03-04-1999	PCT					
WO 99/09973	03-04-1999	PCT		Ì			
WO01/00273	06-23-2000	PCT					

**EXAMINER** 

**Date Considered** 

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Page 3 of 4 INFORMATION Atty. Docket No.: P-9091.04 Serial No.: 10/724,978 **USCLOSURE** ATEMENT Applicant(s): Jahns et al 1-7 2004 Filing Date: 12-01-03 Group: OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.) Coronary Artery Surgery With Induced Temporary Asystole And Intermittent Ventricular Pacing: An Experimental Study / R. Khanna and H.C. Cullen / Cardiovascular Surgery/ April 1996 Vol 4 No. 2 pp: 231-236 Editorial / Adrian R.M. Upton / PACE, October, Part II 1992 Vol. 15 pp: 1543-1544 Neural Effects On Sinus Rate and Atrioventricular Conduction Produced by Electrical Stimulation from a Transvenous Electrode Catheter in the Canine Right Pulmonary Artery / Terry B. Cooper, Gilbert R. Hageman, Thomas N. James, and Albert L. Waldo / Circulation Research Vol. 46, No.1, January 1980 Selective Stimulation of Parasympathetic Nerve Fibers to the Human Sinoatrial Node / Mark D. Carlson, MD, MA; Alexander S. Geha, MD, MS; Jack Hsu, MD; Paul J. Martin, PhD; Matthew N. Levy, MD; Gretta Jacobs, MD; and Albert l. Waldo, MD / Circulation - Vol 85, No 4 pp: 1311-1317 Controlled Intermittent Asysteole: Pharmacologic Potentiation of Vagal-Induced Asystole / Bradley L. Burkin, MD; John D. Puskas, MD; Jakob Vinten-Johansen, PhD; Steven T. Shearer, BS; and Robert A. Guyton, MD / The Society of Thoracic Surgeons - 1998 Controlled Ventricular Asystole With Surgeons – Actuated Pacing For Off-Pump Coronary Artery Bypass Grafting: A Proposed Surgical Method / Francis G. Duhaylongsod and William R. Burfeind, Jr. / IBMCS Abstract – June 25, 1998 Age-Related Changes of Cardiac Control Function in Man: With special reference to heart rate control at rest and during exercise. / Iwao Sato, MD; Yasuhiro Hasegawa, MD; Norikazu Takahashi, MD; Yukio Hirata, MD; Katsuro Shimomura, MD; and Ken Hotta, PhD. / Journal of Gerontology, 1981, Vol. 36, No. 5, pp: 564-572 Cardiac Muscarinic Receptors Decrease with Age / Otto-Erich Brodde; Ulrich Konschak; Karin Becker; Florian Ruter; Ulrike Potter; Jens Jakubetz; Joachim Radke; and Hans-Reinhard Zerkowski / J. Clin. Invest. Volume 101, Number 2. January 1998, 471-478 Age-Dependent Changes in Cardiac Muscarinic Receptor Function in Healthy Volunteers / Ulrike Pller, MD; Gesine Nedelka, MD; Joachim Radke, MD; Klaus Poinicke, Ph.D.; and Otto-Erich Brodde, Ph.D. / JACC Vol. 29. No. 1 January 1997: 187-93 Age-Related Changes of Cardiac Parasympathetic Modulation After Vasovagal Syncope / Alfonso Lagi, MD; Simone Cencetti, MD; Lamberto Fattorini, MD; and Carlo Tamburini, MD / The American Journal of Cardiology Vol. 83 March 15, 1999 Desensitization of the Cholinergic receptor at the sinoatrial cell of the kitten / Jose Jalife; Allan J. Hamilton, and Gordon K. Moe / 1980 the American Physiological Society Sensitivity differences of SA and AV node to vagal stimulation: attenuation of vagal effects at SA node / Jerod M. Loeb; Daniel P. Dalton; and John M. Moran / 1981 the American Physiological

Page; and D. Wilkins / British Journal of Surgery 1997, 84, 854

A New Method For Intraoperative Recurrent Laryngeal Nerve Monitoring / Richard W. Maloney, MD; Benjamin W. Murcek, DO; Kirk W. Steehler, DO; Dennis Sibly; Richard E. Maloney / ENT Journal January 1994

**EXAMINER** 

**Date Considered** 

Vagal Nerve Monitoring: A Comparison of Techniques in a Canine Model / Mark A. Severtson; John P. Leonette; and Denise Jarocki / The American Journal of Otology 18:398-400 1997
The NIM-2 nerve integrity monitor in thyroid and parathyroid surgery / J. Barwell; J. Lytle; R.

<sup>\*</sup>Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

E	NFOI	RMATION	Atty. Docket No.: P-9091.04	Serial No.: 10/724,978				
7	EDISC	LOSURE						
2004 STATEMENT		<b>TEMENT</b>	Applicant(s): Jahns et al					
			Filing Date: 12-01-03 Group:					
AEK								
	OTH		S (Including Authors, Title, Date,					
		Nerve Stimulator /	noval of Stimulating Electrodes Following Long-Term Therapy with the Vagus / Jose Espinosa, MD; Mary T. Aiello, MA; and Dean K. Naritoku, MD / 1999 tnc. / Surg Neurol 1999:51:659-64					
			erve Stimulation by the NCP System, All-Caplained Death / J.F. Annegers; Sharon P. Coa. No.5, 2000					
		Fade of cardiac res	sponses during tonic vagal stimulation / Paul 982 the American Physiological Society	Martin, Matthew N. Levy, and				
		Matheny, MD / pre	Minimally Invasive Cardiac Surgery – Techniques of Stabilization / Robert G.  presented by the Minneapolis Heart Institute Foundation June 19-21, 1997					
		Matheny, MD; and	ulation as a Method to Temporarily Slow or a Carl J. Shaar, PhD / 1997 by The Society of	Thoracic Surgeons				
		Seizures / E. Ben-l	ulation for Treatment of Partial Seizures: 1. A Menachem, R. Manon-Espaillat; R. Ristanov Wernicke; and First International Vagus Ner 16-626, 1994	c; B.J. Wilder; H. Stefan; W. Mirza;				
		/ R.E. Ramsay; B.I G. Barolat; J.F. W 627-636, 1994	ulation for Treatment of Partial Seizures: 2. S. M. Uthman; L.E. Augustinsson; A.R.M. Upto ernicke; and First International Nerve Stimul	n; D. Naritoku; J. Willis; T. Treig; ation Study Group / Epilepsia. 35(3)				
		Patients Exiting a	ulation for Treatment of Partial Seizures: 3. Controlled Study / R. George; M. Salinsky; Rver; J.F. Wernicke; and First International News 37-643, 1994	. Kuzniedky; W. Rosenfeld; D.				
		Against Epilepsy /	ulation for the Control of Epilepsy / Epilepsia Proceedings of a Symposium held I conjunct eeting Boston, MA December 2, 1989					
	_							
	_							
	NATE :			· · · · · · · · · · · · · · · · · · ·				
EXA.	MINE	₹	Date Considered					
			whather ar not citation is in conformance with MDC					

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

Page 4 of 4